

COPY FOR IB

PATENT COOPERATION TREATY

PCT

PCT/KR2004/001493

| |
|-------------------|
| REC'D 03 OCT 2005 |
| WIPO |
| PCT |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

| | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|--------------------------------------------------------------------|
| Applicant's or agent's file reference NPPF04-0828 | FOR FURTHER ACTION | See Form PCT/IPEA/416 |
| International application No. PCT/KR2004/001493 | International filing date (day/month/year) 22 JUNE 2004 (22.06.2004) | Priority date (day/month/year) 23 JUNE 2003 (23.06.2003) |
| International Patent Classification (IPC) or national classification and IPC IPC7 G01N 33/48, G01N 33/49, G01N 15/02, G01N 11/04, G01N 27/00 | | |
| Applicant SEWON MEDITECH, INC. et al | | |

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:

sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____ containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

Box No. I Basis of the report

Box No. II Priority

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Box No. IV Lack of unity of invention

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Box No. VI Certain documents cited

Box No. VII Certain defects in the international application

Box No. VIII Certain observations on the international application

| | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| Date of submission of the demand 04 NOVEMBER 2004 (04.11.2004) | Date of completion of this report 25 AUGUST 2005 (25.08.2005) |
| Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140 | Authorized officer SHIN, Weon Hye Telephone No. 82-42-481-5591 |



Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

This report is based on translations from the original language into the following language English which is the language of a translation furnished for the purposes of:

international search (under Rules 12.3 and 23.1(b))
 publication of the international application (under Rule 12.4)
 international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

the international application as originally filed/furnished

the description:

pages _____ as originally filed/furnished
 pages* _____ received by this Authority on _____
 pages* _____ received by this Authority on _____

the claims:

pages _____ as originally filed/furnished
 pages* _____ as amended (together with any statement) under Article 19
 pages* _____ received by this Authority on _____
 pages* _____ received by this Authority on _____

the drawings:

pages _____ as originally filed/furnished
 pages* _____ received by this Authority on _____
 pages* _____ received by this Authority on _____

the sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. The amendments have resulted in the cancellation of:

the description, pages _____
 the claims, Nos. _____
 the drawings, sheets _____
 the sequence listing (*specify*) : _____
 any table(s) related to sequence listing (*specify*) : _____

4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

the description, pages _____
 the claims; Nos. _____
 the drawings, sheets _____
 the sequence listing (*specify*) : _____
 any table(s) related to sequence listing (*specify*) : _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2004/001493

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

| | | | |
|-------------------------------|--------|------|-----|
| Novelty (N) | Claims | 1-11 | YES |
| | Claims | none | NO |
| Inventive step (IS) | Claims | 1-11 | YES |
| | Claims | none | NO |
| Industrial applicability (IA) | Claims | 1-11 | YES |
| | Claims | none | NO |

2. Citations and explanations (Rule 70.7)

Reference is made to the following documents from the International Search Report (ISR):

D1: US 5798827 A 25 Aug 1998

D2: US 5851835 A 22 Dec 1998

D3: US 5327777 A 12 Jul 1994

Objective of the present invention is to provide an instrument for measuring blood cell deformability, which comprises a disposable blood test kit, a light emitting unit and a measurement unit. The disposable blood test kit is composed of a blood sample pot, a transparent slit channel and a waste blood pot. The instrument adopts a differential pressure to make the stagnant blood sample flow through the slit channel of the test kit and to collect the tested blood sample at the waste blood pot.

1. Novelty

D1 is considered to represent the most relevant state of the art for the present invention, with respect to an apparatus for determination of individual red blood cell shape by measuring the light scatter pattern produced by laser illumination of the cell within the aperture by light scatter detectors and to use of pressurized sample reservoir.

D2 also discloses an apparatus for determination of individual red blood cell shape by detecting the light scatter pattern produced by laser illumination of the cell within the aperture by a CCD camera. However, D2 does not disclose a pressurized apparatus.

D3 relates to a method and an apparatus for biorheological measurements of a suspension of cells, which comprises steps of causing some of the cells to pass through one or more transparent microsize tunnels under a pressure difference between the tunnel ends and monitoring their passage through the tunnels. The apparatus, however, is different from the present invention in that it is a system which has only a measurement unit but not a light emitting unit.

- continued in supplemental box

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2004/001493

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box V

The subject matter of claim 1 contains the disposable blood test kit, of which pots are subjected to pressure differences. Although the apparatus disclosed in D1 seems to have most constituents similar to those of the present invention, D1 does not disclose such a disposable test kit. Therefore, claim 1 and its dependent claims 2-11 fulfill the criteria set forth in Article 33(2) PCT.

2. Inventive step

The technical feature of claim 1 is the disposable nature of the kit. The constituents and structure of the test kit of claim 1 is believed to make the kit amenable to use in a disposable format (see figures 2 & 3). The blood test apparatus disclosed in D1 contains a pressurized reservoir and all other constituents; but the reservoir is not disposable. None of prior art discloses a disposable reservoir. Present invention is non-obvious to those skilled in the art over what D1-D3 disclose and involves an inventive step. Accordingly, claim 1 and its dependent claims 2-11 fulfill the criteria set forth in Article 33(3) PCT.

3. Industrial applicability

Objective of claims 1-11 is to provide an instrument for measuring blood cell deformability, which is an indicator of diseases such as diabetes. There is no reason to negate the industrial applicability of this invention. Consequently, claims 1-11 appear to meet the requirements of Article 33(4) PCT.